



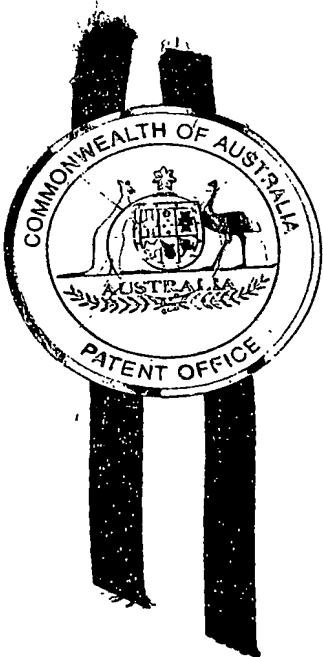
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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PS 3239 for a patent by CHINESE MEDICINES SCIENTIFIC CONSULTANTS PTY LTD as filed on 27 June 2002.

WITNESS my hand this
Eighth day of July 2003

JULIE BILLINGSLEY
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AUSTRALIA

PATENTS ACT 1990

PROVISIONAL SPECIFICATION

FOR THE INVENTION ENTITLED:-

**"COMPOSITIONS AND METHODS FOR TREATING GYNAECOLOGICAL
DISORDERS"**

The invention is described in the following statement:-

TECHNICAL FIELD

This invention relates to new medicinal compositions and methods for treating gynaecological disorders, in particular the treatment or prevention of Endometriosis and Adenomyosis.

5

BACKGROUND

Endometriosis is a gynaecological disorder involving the presence of endometrial cells (i.e. the cells lining the uterus) outside of the lumen of the uterus, at other sites within the cavity of the pelvis; or in the case of adenomyosis, within the muscle wall of the uterus itself. These fragments of abnormally located tissue ('endometriotic lesions') pass through the same periodic changes as the uterine lining, but lack an outlet for the bleeding that occurs from them. The presence of free blood within the pelvic cavity or within the muscle wall of the uterus can lead to severe pain and numerous complications such as the formation of adhesions, increase in size and bulk of the uterus, and stricture of fallopian tubes or bowel.

The current treatment is surgical followed by menstrual suppression, now predominantly via the contraceptive pill.

It is an object of the present invention to ameliorate at least some of the disadvantages of the prior art therapies and methods, or at least provide useful alternatives.

SUMMARY OF THE INVENTION

The formulations of the present invention are designed to provide a treatment and/or prevention for recurrent Endometriosis, and/or alleviate the symptoms of recurrent Endometriosis or Adenomyosis. In particular, the present invention can alleviate pelvic discomfort following several surgical interventions for Endometriosis or Adenomyosis.

Accordingly, in a first aspect, the present invention provides a composition including the herbs

<i>Chi Shao</i>	(<i>Paeonia obovata</i> , Root)
<i>Dang Gui</i>	(<i>Angelica Polymorpha</i> , Root)
<i>Chuan Xiong</i>	(<i>Ligusticum Wallichii</i> , Root)
<i>Xiang Fu</i>	(<i>Cyperus Rotundus</i> , Rhizome)

30

Yan Hu Suo (Corydalis turtschaninovii, Rhizome)

Tao Ren (Prunus persica, Seed), or parts thereof.

According to a second aspect, the present invention provides a composition including the herbs Paeonia obovata, Ligusticum wallichii, Angelica Polymorpha, Cyperus Rotundus, Corydalis turtschaninovii, Prunus persica, Poria cocos, Alisma plantago-aquatica, Atractylodes macrocephala, Spatholobus suberectus, Lindera Strychnofolia, Glycyrrhiza uralensis, or parts thereof.

The compositions set out above may be supplemented with one or more herbs selected from the group consisting of:

- | | | |
|----|-----------------------|--|
| 10 | <i>Bai Shao</i> | (Paeonia lactiflora, root) |
| | <i>Sheng Di</i> | (Rehmannia glutinosa, root) |
| | <i>Shou Di</i> | (Rehmanniae glutinosae conquitae, root) |
| | <i>Gou Qi Zi</i> | (Lycium chinensis, fruit) |
| 15 | <i>Fang Feng</i> | (Ledebouriella seseloides, root) |
| | <i>Chen Pi</i> | (Citrus reticulata, fruit pericarp) |
| | <i>Chai Hu</i> | (Bupleurum falcatum, root) |
| | <i>Xu Duan</i> | (Dipsacus asper, root) |
| | <i>Ye Jiao Teng</i> | (Polygonum Multiflorum, vine stem) |
| 20 | <i>Tu Si Zi</i> | (Cuscuta, Seed) |
| | <i>Shan Zha</i> | (Crataegus cuneata, fruit) |
| | <i>He Huan Pi</i> | (Albizziae julibrissin, bark) |
| | <i>Yi Mu Cao</i> | (Leonurus sibiricus, Herb) |
| | <i>Tian Qi</i> | (Panax pseudoginseng, Root) |
| 25 | <i>Hong Hua</i> | (Carthamus tinctorius, Flos) |
| | <i>Sang Ji Sheng</i> | (Loranthus parasiticus, Stem) |
| | <i>Xiao Hui Xiang</i> | (Foeniculum Vulgare, Fruit) |
| | <i>Gui Zhi</i> | (Cinnamomum cassia, stem), or parts thereof. |

The above supplementary herbs may be conveniently grouped into subsets, and as such added to the compositions of the first or second aspect, for treatment of particular conditions. The preferred subsets are as follows:

Subset a: 'Endometriosis with blood deficiency and poor immunity'

- Bai Shao* (Paeonia lactiflora, root)
Sheng Di (Rehmannia glutinosa, root)
Shou Di (Rehmanniae glutinosae conquitae, root)
 5 *Gou Qi Zi* (Lycium chinensis, fruit)

Subset b: 'Endometriosis affecting the bowels'

- Fang Feng* (Ledebouriella seseloides, root)
Chen Pi (Citrus reticulata, fruit pericarp)
Shan Zha (Crataegus cuneata, fruit)

10 *Subset c: 'Endometriosis with anxiety'*

- Chai Hu* (Bupleurum falcatum, root)
Ye Jiao Teng (Polygonum multiflorum, vine stem)
He Huan Pi (Albizziae julibrissin, bark)

Subset d: 'Endometriosis with lower back ache'

- 15 *Xu Duan* (Dipsacus asper, root)
Tu Si Zi (Cuscuta, Seed)
Sang Ji Sheng (Loranthus parasiticus, Stem)

Subset e: 'Endometriosis with severe menstrual clotting and/or pelvic congestion'

- 20 *Yi Mu Cao* (Leonurus sibiricus, Herb)
Tian Qi (Panax pseudoginseng, Root)
Hong Hua (Carthamus tinctorius, Flos)

Subset f: 'Endometriosis with cold pain'

- Xiao Hui Xiang* (Foeniculum Vulgare, Fruit)
 25 *Gui Zhi* (Cinnamomum cassia, stem)

It will be understood however, that the conditions identified for treatment with formulations containing the various subsets of herbs need not be as designated above. The designations are provided merely as an example of preferred groupings and possible indications of use.

- 30 Preferably, the compositions are formulated with dried herbs which can be decocted for use by the patient. Herbs may also be in powdered form. However, the compositions of the present invention can also be

formulated with aqueous, organic or aqueous/organic extracts of the herbs, which extracts may be dried and formulated by conventional means. The composition may also be delivered in a capsule or tablet dosage form, but it can also be delivered in a liquid or paste form. The
5 composition may further include pharmaceutically acceptable excipients, adjuvants, solvents, carriers, flavours, colourings or coatings (suitable excipients, adjuvants, solvents, carriers, flavours, colourings and coatings my found in standard texts such as for example Remington: The Science and Practice of Pharmacy, 19th Ed., Mack Publishing Co., 1995,
10 incorporated in its entirety herein by reference).

According to a third aspect, the present invention provides a method of therapeutic or prophylactic treatment of a gynaecological disorder including the administration to a subject requiring such treatment a composition according to the first or second aspect.

15 According to a fourth aspect, the present invention provides a method of alleviating a symptoms resulting from a gynaecological disorder including the administration to a subject requiring such treatment a composition according to the first or second aspect.

According to a fifth aspect, the present invention provides a method
20 of therapeutic or prophylactic treatment of endometriosis and/or adenomyosis including the administration to a subject requiring such treatment a composition according to the first or second aspect.

According to a sixth aspect, the present invention provides a method
25 of alleviating a symptoms resulting from endometriosis and/or adenomyosis including the administration to a subject requiring such treatment a composition according to the first or second aspect.

It is preferable that the treatment is administered orally. The treatment may be administered in a single bolus dose, multiple doses or via a slow release device.

30 According to a seventh aspect, the present invention provides a composition according to the first or second aspect for use as a medicament.

According to an eighth aspect, the present invention provides the use of a composition according to the first or the second aspect for the

manufacture of a medicament for prophylactic or therapeutic treatment of a gynaecological disorder.

According to a ninth aspect, the present invention provides the use of a composition according to the first or the second aspect for the
5 manufacture of a medicament for prophylactic or therapeutic treatment of endometriosis and/or adenomyosis.

It will be understood by those skilled in the art that the formulations of the present invention may be suitably used, and be effective in the treatment not only of endometriosis but also of a related condition,
10 adenomyosis. Hence, when referring to the preferred "Endometriosis formulation", it is intended that such a formulation also applies to adenomyosis.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The treatment of medical disorders using herbal formulations differs
15 from orthodox Western-style treatments in that the herbal formulations are intended to be tailored to meet the specific requirements of each patient. These case studies illustrate the way in which a base formulation may be adjusted to treat Endometriosis or general disturbances in the menstrual cycle typified by PMS and/or dysmenorrhoea and the resulting symptoms
20 which may manifest in a patient suffering these conditions.

The components of a core formulation (see examples) may be supplemented with one or more additional herbs. Specific tailored formulations, including the core and additional supplementary herbs, which may usefully be prescribed for treatment, are also included as individual
25 embodiments of the present invention. One such formulation described herein is the preferred formulation (also referred to as the "endometriosis formulation"). Further formulations for treating Endometriosis and other gynaecological conditions with specific symptom-patterns, eg 'Endometriosis pain with lower back discomfort' or 'Endometriosis irritating
30 the bowel', can be created using the core and supplementary components described herein.

Thus, the supplementary herbs are not crucial to the treatment, but for convenience, and without limitation, may be grouped (see examples).

Typically, one to six more herbs may be chosen from additional set, depending on patient's symptoms and needs of the treatment.

Preferred embodiments of the invention will now be described by way of example only with reference to the following case studies.

5

EXAMPLES

Example 1: Formulations and preparation

The components of a core set of herb useful in the preparation of the formulations of the present invention are listed in Table 1 below. Omission of one or more of the core set may make the formulation less effective in the treatment.

10

Table 1: Core herbs

<u>Chinese name</u>	<u>Pharmaceutical name</u>
<i>Chi Shao</i>	(<i>Paeonia obovata</i> , Root)
<i>Dang Gui</i>	(<i>Angelica Polymorpha</i> , Root)
15 <i>Chuan Xiong</i>	(<i>Ligusticum Wallichii</i> , Root)
<i>Xiang Fu</i>	(<i>Cyperus Rotundus</i> , Rhizome)
<i>Yan Hu Suo</i>	(<i>Corydalis turtschaninovii</i> , Rhizome)
<i>Tao Ren</i>	(<i>Prunus persica</i> , Seed)

The most preferred formulation for treatment of Endometriosis and/or Adenomyosis is set out in Table 2 below:

20

Table 2: Preferred formulation ("Endometriosis formulation")

<u>Chinese name</u> (grams)	<u>Pharmaceutical name</u>	<u>dosage range</u>
Chi Shao	<i>Paeonia obovata</i> , root	6-30
25 Fu Ling	<i>Poria cocos</i> , sclerotium	6-20
Ze Xie	<i>Alisma plantago-aquaticae</i> , rhizome	6-20
Dang Gui	<i>Angelica polymorpha</i> , root	6-12
Bai Zhu	<i>Atractylodes macrocephala</i> , rhizome	6-15
Chuan Xiong	<i>Ligusticum wallichii</i> , root	6-12
30 Xiang Fu	<i>Cyperus rotundus</i> , rhizome	6-15
Yan Hu Suo	<i>Corydalis turtschaninovii</i> , rhizome	6-15

Tao Ren	Prunus persica, seed	6-12
Ji Xue Teng	(Spatholobus suberectus, root & stem)	12-30
Wu Yao	(Lindera strychnofolia, root)	6-15
Gan Cao	(Glycyrrhiza uralensis, root)	1-6

5 Chi Shao can be replaced, in total or partially, by Bai Shao (*Paeonia lactiflora*, root). Bai Shao is simply the cultivated form of Chi Shao. Ji Xue Teng (*Spatholobus suberectus*, root & stem) could be replaced by Hong Teng (*Sargentodoxa cuneata*, vine stem).

10 The herbs may be used most simply as dried raw herbs. Thus used the herbs are weighed out and given to the patient in a bag to take home to decoct (boil in water) themselves. Typical instructions are to boil the herbs 3 times, for 40 minutes each time in approximately 500 mL of water, then combine the decoctions. 100 - 150 mL (depending upon the patient's digestive strength) is then decanted and consumed in the morning and
15 again in the evening.

In the preferred formulations the only herb prepared beyond the raw stage is *Yan Hu Suo* (*Corydalis turtschaninovii*, rhizome), which may be soaked in vinegar (for example undiluted rice vinegar) overnight, then baked dry in an oven at about 180° until thoroughly dry. This increases the
20 availability of the alkaloid *corydaline* and thus improves the analgesic effect.

The herbs may also be formulated from extracts, individual or combined. Thus, the volatile oils may be extracted from the appropriate herbs (for example Dang Gui and Xiang Fu) typically by distillation, but
25 may also be extracted by solvent systems based on volatile solvents such as petroleum ether, benzene and the like. The exact method of extracting volatile oils depends upon the type of herb and those skilled in the art would be able to choose the appropriate method from a number of methods known in the art.

30 The extracts are separated from the extracted herbs and the extracted herbs are then combined with the remaining herbs and the whole formula is decocted (boiled in water) twice. The first decoction uses a greater amount of water (approximately 8 times the amount of water to the weight of the raw herbs, to allow for absorption into the dried herb

material) to decoct for 1.5 hours, the second time uses somewhat less water (approximately 6 times the amount of water to weight of the dried herbs) to decoct for 1 hour. The resulting liquids remaining after boiling are combined, mixed and filtered, then concentrated at low heat. The resulting liquid is filtered again, spray-dried and the resulting dried particles then sprayed with the volatile oils extracted earlier, and tested to meet the required specifications.

Certain additional herbs, which can be used in conjunction with the core set, or in conjunction with the preferred formulation, are listed in Table 3 below. One or more additional herbs, typically one to six additional herbs, selected from those listed in Table 3, assist in addressing the symptoms peculiar to the individual patient. The additions are appropriate in prescriptions customized for individual patients.

Table 3: Preferred additional herbs.

15	<i>Bai Shao</i>	(<i>Paeonia lactiflora</i> , root)
	<i>Sheng Di</i>	(<i>Rehmannia glutinosa</i> , root)
	<i>Shou Di</i>	(<i>Rehmanniae glutinosae conquitae</i> , root)
	<i>Gou Qi Zi</i>	(<i>Lycium chinensis</i> , fruit)
	<i>Fang Feng</i>	(<i>Ledebouriella seseloides</i> , root)
20	<i>Chen Pi</i>	(<i>Citrus reticulata</i> , fruit pericarp)
	<i>Chai Hu</i>	(<i>Bupleurum falcatum</i> , root)
	<i>Xu Duan</i>	(<i>Dipsacus asper</i> , root)
	<i>Ye Jiao Teng</i>	(<i>Polygonum Multiflorum</i> , vine stem)
	<i>Tu Si Zi</i>	(<i>Cuscuta</i> , Seed)
25	<i>Shan Zha</i>	(<i>Crataegus cuneata</i> , fruit)
	<i>He Huan Pi</i>	(<i>Albizziae julibrissin</i> , bark)
	<i>Yi Mu Cao</i>	(<i>Leonurus sibiricus</i> , Herb)
	<i>Tian Qi</i>	(<i>Panax pseudoginseng</i> , Root)
	<i>Hong Hua</i>	(<i>Carthamus tinctorius</i> , Flos)
30	<i>Sang Ji Sheng</i>	(<i>Loranthus parasiticus</i> , Stem)
	<i>Xiao Hui Xiang</i>	(<i>Foeniculum Vulgare</i> , Fruit)
	<i>Gui Zhi</i>	(<i>Cinnamomum cassia</i> , stem)

One or more herbs from the above list can be used to create further "Endometriosis" formulations, depending on which additional symptoms need treatment. Not wishing to be bound by any theory or proposed mechanisms of action, the herbs set out in Table 3 may be conveniently grouped into sub-sets for specific indications.

Subset a: 'Endometriosis with blood deficiency and poor immunity'

	<i>Bai Shao</i>	(<i>Paeonia lactiflora</i> , root)
	<i>Sheng Di</i>	(<i>Rehmannia glutinosa</i> , root)
	<i>Shou Di</i>	(<i>Rehmanniae glutinosae conquitae</i> , root)
5	<i>Gou Qi Zi</i>	(<i>Lycium chinensis</i> , fruit)

Subset b: 'Endometriosis affecting the bowels'

	<i>Fang Feng</i>	(<i>Ledebouriella seseloides</i> , root)
	<i>Chen Pi</i>	(<i>Citrus reticulata</i> , fruit pericarp)
	<i>Shan Zha</i>	(<i>Crataegus cuneata</i> , fruit)

Subset c: 'Endometriosis with anxiety'

	<i>Chai Hu</i>	(<i>Bupleurum falcatum</i> , root)
	<i>Ye Jiao Teng</i>	(<i>Polygonum multiflorum</i> , vine stem)
	<i>He Huan Pi</i>	(<i>Albizziae julibrissin</i> , bark)

Subset d: 'Endometriosis with lower back ache'

20	<i>Xu Duan</i>	(<i>Dipsacus asper</i> , root)
	<i>Tu Si Zi</i>	(<i>Cuscuta</i> , Seed)
	<i>Sang Ji Sheng</i>	(<i>Loranthus parasiticus</i> , Stem)

Subset e: 'Endometriosis with severe menstrual clotting and/or pelvic congestion'

25	<i>Yi Mu Cao</i>	(<i>Leonurus sibiricus</i> , Herb)
	<i>Tian Qi</i>	(<i>Panax pseudoginseng</i> , Root)
	<i>Hong Hua</i>	(<i>Carthamus tinctorius</i> , Flos)

Subset f: 'Endometriosis with cold pain'

	<i>Xiao Hui Xiang</i>	(<i>Foeniculum Vulgare</i> , Fruit)
30	<i>Gui Zhi</i>	(<i>Cinnamomum cassia</i> , stem)

Example 2: Case Study 1.

Presentation.

Patient 1 was 23 years of age. At presentation she had suffered with Endometriosis for two years during which time she had undergone two laparoscopies with laser treatment for extensive and severe endometriotic lesions. She was prescribed Danocrine from which she suffered dizziness, weight gain, hot flushing and thirst. As a result of the Endometriosis she suffered lower abdominal stabbing pain in the lower right quadrant, and fluid retention. The initial prescription considered both the Endometriosis-associated pain and the side effects of the medication.

Prescription 1 (# 3096) for Case Study 1.

	<u>Chinese name</u>	<u>Pharmaceutical name</u>	<u>Dried Herb</u>
10	<i>Fu Ling</i>	Poria cocos, Sclerotium	12g
	<i>Ze Xie</i>	Alisma plantago-aquatica, Rhizome	15g
	<i>Dang Gui</i>	Angelica polymorpha, Radix	12g
	<i>Bai Zhu</i>	Atractylodes macrocephala, Rhizoma	12g
15	<i>Xiang Fu</i>	Cyperus rotundus, Rhizome	12g
	<i>Yan Hu Suo</i>	Corydalis turtchaninovii, Rhizome	12g
	<i>Gan Cao</i>	Glycyrrhizae uralensis, Radix	3g
	<i>He Huan Pi</i>	Albizzia julibrissin, bark	15g
	<i>Yu Jin</i>	Curcumae, Tuber	12g
20	<i>Ren Dong Teng</i>	Lonicerae Japonicae, Ramus	18g
	<i>Chuan Lian Zi</i>	Meliae Toosendan, Fructus	12g
	<i>Fo Shou Pian</i>	Citrii Sarcodactylis, Fructus	6g
	<i>Ban Xia</i>	Pinelliae Ternata, Rhizoma	12g
	<i>Shi Chang Pu</i>	Acori Graminei, Rhizoma	12g
25	<i>Shen Qu</i>	Massa Fermentata	15g

Dosage: 100mls of decoction in the morning and evening.

Second Consultation

At the second consultation two weeks later, the patient reported a reduction in the side-effects of the medication Danocrine, and less severe Endometriosis-associated pain. Based on these observations the prescription was customized further for her specific requirements. She was advised to take prescription 2.

Prescription 2 (#3162) for Case Study 1:

	<u>Chinese name</u>	<u>Pharmaceutical name</u>	<u>Dried Herb</u>
	<i>Chi Shao</i>	<i>Paeonia obovata</i> , Radix	9g
	<i>Bai Shao</i>	<i>Paeonia lactiflora</i> , Radix	9g
5	<i>Fu Ling</i>	<i>Poria cocos</i> , Sclerotium	15g
	<i>Ze Xie</i>	<i>Alisma plantago-aquatica</i> , Rhizoma	12g
	<i>Dang Gui</i>	<i>Angelica polymorpha</i> , Radix	12g
	<i>Bai Zhu</i>	<i>Atractylodes macrocephala</i> , Rhizome	15g
	<i>Chuan Xiong</i>	<i>Ligusticum wallichii</i> , Radix	12g
10	<i>Xiang Fu</i>	<i>Cyperus rotundus</i> , Rhizoma	12g
	<i>Yan Hu Suo</i>	<i>Corydalis turtshaninovii</i> , Rhizoma	2g
	<i>Gan Cao</i>	<i>Glycyrrhiza uralensis</i> , Radix	3g
	<i>He Huan Pi</i>	<i>Albizzia julibrissin</i> , bark	15g
	<i>Chai Hu</i>	<i>Bupleurum falcatum</i> , Root	6g
15	<i>Chen Pi</i>	<i>Citrus Reticulata</i> , pericarpium	6g
	<i>Fo Shou Pian</i>	<i>Citrii Sarcodactylis</i> , Fructus	6g
	<i>Chuan Lian Zi</i>	<i>Meliae Toosendan</i> , Fructus	9g
	<i>Hong Teng</i>	<i>Caulis Sargentodoxae Cuneatae</i>	18g
	<i>Gui Zhi</i>	<i>Cinnamomi Cassiae</i> , Ramulus	9g

20

Dosage as for above (ie. 100mls of decoction morning and evening)

Third Consultation.

At the third consultation four weeks later the patient reported feeling very well and the disappearance of abdominal pain apart from occasional slight twinges. She was able to stop taking Danocrine and had not taken it for three weeks leading up to the consultation. She was advised to repeat administration of prescription 2.

25

Fourth Consultation.

Two months later she obtained a repeat prescription. She reported only one day of severe pain which was the second day of her last period.

30

Fifth Consultation.

Ten months later she called and reported that she had been feeling exceptionally well. She had taken the contraceptive pill for 6 months and

noticed some pain after discontinuing use. She was advised to take a repeat of prescription 2.

At a follow-up consultation she reported that she had not suffered any endometriosis-related pain. Ultrasound scans found no trace of residual Endometriosis. Twelve months of treatment with the herbal formulation had successfully resolved her condition.

Example 3: Case Study 2 (Prescription #4610)

Presentation.

Patient 2 was 30 years of age. Endometriosis had been diagnosed 5 years prior to presentation. She had undergone a laparoscopy, fallen pregnant and had not had a problem until recently at which she reported having Endometriosis pain from 'umbilicus to toes'. The pain was worse at night than during the day. She was advised to take the following prescription:

	<u>Chinese name</u>	<u>Pharmaceutical name</u>	<u>Dried Herb</u>
15	<i>Chi Shao</i>	<i>Paeonia obovata</i> , Radix	9g
	<i>Bai Shao</i>	<i>Paeonia lactiflora</i> , Radix	9g
	<i>Dang Gui</i>	<i>Angelica polymorpha</i> , Radix	9g
	<i>Chuan Xiong</i>	<i>Ligusticum wallichii</i> , Radix	9g
20	<i>Xiang Fu</i>	<i>Cyperus rotundus</i> , Rhizoma	12g
	<i>Yan Hu Suo</i>	<i>Corydalis turtschaninovii</i> , Rhizoma	9g
	<i>Tao Ren</i>	<i>Prunus persica</i> , Semen	9g
	<i>Ji Xue Teng</i>	<i>Spatholobus suberectus</i> , Radix et Caulis	15g
	<i>Ye Jiao Teng</i>	<i>Polygonum multiflorum</i> , vine stem	30g
25	<i>He Huan Pi</i>	<i>Albizzia julibrissin</i> , bark	18g
	<i>Chai Hu</i>	<i>Bupleurum falcatum</i> , Root	6g
	<i>Sheng Di</i>	<i>Rehmannia glutinosa</i> , Radix	15g
	<i>Fo Shou Pian</i>	<i>Citrii Sarcodactylis</i> , Fructus	6g
	<i>Mu Dan Pi</i>	<i>Moutan Radicis</i> , Cortex	9g
30	<i>San Leng</i>	<i>Sparganii</i> , Rhizoma	9g
	<i>E Zhu</i>	<i>Curcumae Zedoariae</i> , Rhizoma	9g

Dosage: 150mls decoction morning and evening.

Usually a smaller dose is given if there is a suspicion that a patient may have trouble with the taste of the decoction. This is usually not a problem with the tablets or capsules made from extracts. In case of tablet, capsule and the like formulations, the dosage can be standardised.

5 **Second Consultation.**

At the second consultation four months later four months later, the patient reported that she had not experienced any Endometriosis pain since taking the prescription. She reported having some nausea and headaches prior to her periods, as she had historically always had.

10 **Third Consultation.**

The third consultation took place thirteen months later for a reason unrelated to Endometriosis. She did report that she had only had mild Endometriosis symptoms on 3 occasions in the time since the second consultation.

15 **Example 4: Case Study 3**

Presentation.

Patient 3 was 24 years of age. At presentation Endometriosis had been diagnosed two months previously. Her symptoms included primary dysmenorrhoea involving the abdomen, thighs and lower back, dyspareunia; abdominal bloating and distension everyday, as well as hot flushes, thirst and some palpitations. Menarche was at 11 years of age. Her menstrual cycle was typically 21 days and her period lasted 6-7 days with medium heavy bleeding, preceded by fluid retention and increased abdominal bloating. Her pulse was deep, slippery and rapid. Her tongue had a thin coating and a red tip. She was advised to take the following prescription:

Prescription 1 (# 4255) for case study 3:

	<u>Chinese name</u>	<u>Pharmaceutical name</u>	<u>Dried Herb</u>
	<i>Chi Shao</i>	Paeonia obovata, Radix	9g
30	<i>Bai Shao</i>	Paeonia lactiflora, Radix	9g
	<i>Fu Ling</i>	Poria cocos, Sclerotium	15g
	<i>Ze Xie</i>	Alisma plantago-aquatica, Rhizoma	15g

	<i>Dang Gui</i>	Angelica polymorpha, Radix	12g
	<i>Bai Zhu</i>	Atractylodes macrocephala, Rhizoma	12g
	<i>Chuan Xiong</i>	Ligusticum wallichii, Radix	9g
	<i>Xiang Fu</i>	Cyperus rotundus, Rhizoma	12g
5	<i>Yan Hu Suo</i>	Corydalis turtschaninovii, Rhizoma	12g
	<i>Tao Ren</i>	Prunus persica, Semen	9g
	<i>Ji Xue Teng</i>	Spatholobus suberectus, Radix et Caulis	12g
	<i>Wu Yao</i>	Lindera strychnofolia, Radix	12g
	<i>Gan Cao</i>	Glycyrrhizae uralensis, Radix	3g
10	<i>Shen Qu</i>	Massa Fermentata	15g
	<i>Xiao Hui Xiang</i>	Foeniculi Vulgaris, Fructus	3g
	<i>Da Huang</i>	Rhei, Rhizoma	9g

Dosage: 120 mls of decoction in the morning and evening.

15 This patient was provided with 3 bags of herbs. (Each of the herbs in the list above is measured out at the weight specified and placed in a bag for the patient to take home and decoct. One bag usually provides enough herbal liquid to last 3-4 days at the dosage indicated.).

Second Consultation.

20 At the second consultation the patient reported that she experienced no Endometriosis pain with her last period. Also, the abdominal bloating was reduced with administration of the prescription. She reported still being thirsty, but experienced fewer palpitations. Her pulse was deep and rapid, and the front of her tongue red. She was
25 advised to take the same prescription again.

Third Consultation.

The third consultation took place three weeks later. She reported feeling well despite not taking the prescription. She was advised to continue taking the prescription.

30 **Fourth Consultation.**

The fourth consultation took place six months later. The patient reported having no endometriosis pain for several months but then her pain with the period and with intercourse gradually returned. The patient

required further consolidation of her condition and was advised to take prescription 2.

Prescription 2 (#5532) for Case Study 3:

	<u>Chinese name</u>	<u>Pharmaceutical name</u>	<u>Dried Herb</u>
5	<i>Bai Shao</i>	<i>Paeonia lactiflora</i> , Radix	9g
	<i>Chi Shao</i>	<i>Paeonia obovata</i> , Radix	9g
	<i>Fu Ling</i>	<i>Poria cocos</i> , Sclerotium	15g
	<i>Ze Xie</i>	<i>Alisma plantago-aquatica</i> , Rhizoma	15g
	<i>Dang Gui</i>	<i>Angelica polymorpha</i> , Radix	12g
10	<i>Xiang Fu</i>	<i>Cyperus rotundus</i> , Rhizoma	12g
	<i>Yan Hu Suo</i>	<i>Corydalis turtshchaninovii</i> , Rhizoma	12g
	<i>Ji Xue Teng</i>	<i>Spatholobus suberectus</i> , Radix et Caulis	15g
	<i>Wu Yao</i>	<i>Lindera strychnofolia</i> , Radix	2g
	<i>Gan Cao</i>	<i>Glycyrrhiza Uralensis</i> , Radix	3g
15	<i>Da Huang</i>	<i>Rhei</i> , Rhizoma	9g
	<i>Shen Qu</i>	Massa Fermentata	15g
	<i>Mu Xiang</i>	<i>Saussureae seu Vladimiriae</i> , Radix	12g
	<i>Xiao Hui Xiang</i>	<i>Foeniculi Vulgaris</i> , Fructus	3g

20 **Example 4: Case Study 4.**

Presentation

25 Patient 4 was 40 years of age. She had suffered painful periods for three years and eight months. Endometriosis was diagnosed by laparoscopy at 6 months from pain commencing. Her doctor informed her that it was extensive. Laser treatment followed to remove the Endometriosis lesions. The sustained symptoms included pain in waves, every ten minutes during her periods, which were heavy with dark red clotting. Her menstrual cycle was 24-25 days and her period lasted 4-5 days. Her period was preceded by breast distension, fluid retention and 30 headache. She also complained of chest ache in the cold, and lower backache at times. Her pulse was deep, slippery and somewhat rapid and weak at the chi position. Her tongue was slightly red and thinly coated. Her

immediate concern was the chest ache and rib pain for which she was prescribed a prescription specifically for this purpose.

Second Consultation.

The second consultation was three months later. The patient reported that she was no-longer experiencing chest and rib pain. Her Endometriosis pain was, however, at the umbilical level, and she described it as a sharp intermittent twisting-like gripping. She reported that the pain improved with the application of heat and was worse when sitting down. She also experienced lumbar pain. She reported reduced PMS symptoms except that her breasts were still sore. She was advised to take the following prescription which was formulated to treat Endometriosis:

Prescription #4291

	<u>Chinese name</u>	<u>Pharmaceutical name</u>	<u>Dried Herb</u>
	<i>Chi Shao</i>	Paeonia obovata, Radix	9g
15	<i>Bai Shao</i>	Paeonia lactiflora, Radix	9g
	<i>Fu Ling</i>	Poriae cocos, Sclerotium	18g
	<i>Dang Gui</i>	Angelica polymorpha, Radix	12g
	<i>Chuan Xiong</i>	Ligusticum wallichii, Radix	9g
	<i>Xiang Fu</i>	Cyperus rotundus, Rhizoma	12g
20	<i>Yan Hu Suo</i>	Corydalis turtschaninovii, Rhizoma	12g
	<i>Tao Ren</i>	Prunus persica, Semen	9g
	<i>Ji Xue Teng</i>	Spatholobus suberectus, Radix et Caulis	12g
	<i>Wu Yao</i>	Lindera strychnofolia, Radix	15g
	<i>Gan Cao</i>	Glycyrrhiza Uralensis, Radix	3g
25	<i>He Huan Pi</i>	Albizziae julibrissin, bark	15g
	<i>Chuan Duan</i>	Dipsacus asper, root	12g
	<i>Sang Ji Sheng</i>	(Loranthus parasiticus, Stem)	15g
	<i>Ba Ji Tian</i>	Morindae Officianalis, Radix	12g

30 Dosage: 150mls of decoction morning and evening.

Third Consultation.

The third consultation was 10 weeks later. The patient reported that she experienced only a twinge of discomfort, less clotting and few PMS

symptoms with her last two periods. She also reported the absence of any ordinary period pain.

The patient was advised to repeat the prescription.

Fourth Consultation.

5 The fourth consultation was 7 weeks later. The patient reported only slight discomfort with her last period. Her lower back was still painful and she was still experiencing premenstrual breast distension. She was advised to repeat the prescription.

Fifth Consultation.

10 The fifth consultation was 8 weeks later. The patient reported no pain with her last period. Her lower back had improved and her breasts were still slightly sore.

Nineteen months after the fifth consultation the patient reported that she was feeling very well and that she was not experiencing any
15 Endometriosis pain at all. Six months of treatment with the herbal formulation had successfully resolved her condition.

The present invention has been described with reference to specific preferred embodiments. It will be understood by those skilled in the art that variations in keeping with the principles and spirit of the invention are
20 also encompassed herein.

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